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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,916	03/23/2007	Mitsuru Maeda	47234-5004-00 (219778)	1465
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EXAMINER				
LEITH, PATRICIA A				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/561,916

Applicant(s)

MAEDA ET AL.

Examiner

Patricia Leith

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10 is/are pending in the application.
- 4a) Of the above claim(s) 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on __ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SE-US)
Paper No(s)/Mail Date 10/21/2009
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-8 and 10 are pending in the application.

Claim 10 remains withdrawn from the merits as being directed toward a non-elected invention, elected with traverse in the reply filed on 2/11/2009.

Specification

The Examiner acknowledges Applicants' substitute Specification which capitalizes all instances of any Trademarked goods as well as corrects informal matters. The Substitute Specification has been entered.

Applicants have further made clear that the published PCT Abstract is canceled, thereby leaving one Abstract in this application.

Applicants' actions have therefore overcome the previous Objections made to the Specification.

Rejections Removed

The previous rejection made over claims 6 and 7 under 35 USC 112 Second paragraph have been removed due to Applicants' amendment to these claims adding 'or processed koji.'

The previous rejection made over claim 9 under 35 USC 112 Second has been removed due to the cancellation of claim 9 subsequently rendering said rejection moot.

The previous rejection of claim 8 under 35 USC 112 Second has been removed due to Applicants' amendment to claim 8 to replace 'set of a composition' with – kit --. Applicants' remarks concerning this amendment were fully considered. It is agreed that pages 18-19 comprise support for a kit, even though the specification does not specifically recite the term 'kit.' However, it is also noted that even though the claim states 'kit' the claim does not state that the components are separated in the kit, and therefore, the claim is broad enough to read on wherein the kit contains both ingredients together, or separately.

The previous rejections set forth under 35 USC 103(a) using Maeda et al. (WO 03/057707) are hereby removed. Applicants' arguments are convincing in that this reference was published less than one year prior to Applicants' US filing date and that the inventors in the WO document are the same inventors of this application. Hence, the use of this reference was not 'by another' and was inadvertently used by the Examiner.

A new rejection follows; hence rendering this case non-final.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al. (JP 05013647 – full translation) in view of Shimono et al. (JP 06263790 A (English Abstract, a full translation has been ordered)).

It is noted that the Ito et al. reference is the same reference as the previously cited 'Hara et al.' reference. It can now be seen from the translated version of this Japanese patent that Ito is the first Inventor listed on the patent and henceforth, this reference shall be referred to as 'Ito et al.'. Additionally, the full translation has been received and is attached hereto.

Ito et al. (JP 05013647) disclosed a Vitamin C rich fruit juice drink comprising fruit juice, kojic acid prepared by fermenting *Aspergillus oryzae* and ascorbic acid (see entire reference, especially p. 4 of the full translation).

The phrase 'processed koji' is given its broadest interpretation within reason, consistent with the specification. The Specification does not provide any strict definition for the phrase 'processed koji,' but rather indicates that a 'processed koji' may be any crude extract or isolated compound from koji (koji mold). Kojic acid, found in the fruit juice drink composition of Ito et al. is a compound isolated from koji mold (a

fermentation made with *Aspergilli oryzae*) Additionally, while Applicants do not explicitly state 'processed koji mold,' it appears, from the state of the art that 'koji' and 'koji mold' are the same and the terms 'koji' and 'koji mold' are used interchangeably to mean 'koji mold.' Applicants' Specification itself indicates that a 'processed koji' may be an extract from a koji mold ([0051]).

Ito et al. did not teach the incorporation of 2-O-(β -D-glucopyranosyl) ascorbic acid.

2-O-(β -D-glucopyranosyl) ascorbic acid was a known compound at the time the Invention was made according to Shimono et al. (JP 06263790 A – see English Abstract of this Japanese Patent, a full translation has been ordered). While Shimono et al. disclosed this compound as 2-O-(β -D-glucopyranosyl) L ascorbic acid, the compound disclosed by Shimono et al. appears to be a structurally equivalent compound to 2-O-(β -D-glucopyranosyl) ascorbic acid as encompassed by Applicants' claims. Shimono et al. touted this compound as exhibiting excellent stability useful as a stabilizer, quality improver antioxidant and UV-absorbent. Shimono et al. prepared a grape fruit juice soft drink containing this compound and further used this compound to prepare gum, toothpaste, troches, mouth wash and cream (again, see English abstract).

One of ordinary skill in the art would have been motivated to substitute the ascorbic acid (vitamin C) for the provitamin C compound 2-O-(β -D-glucopyranosyl)

ascorbic acid as disclosed by Shimono et al.. due to the superior stability of this vitamin C compound. Clearly, the ordinary artisan, having the above-cited references before him or her would have recognized the advantage of formulating a fruit juice composition which had excellent stability and antioxidant capabilities. "[A] person of ordinary skill is also a person of ordinary creativity, not an automaton *KSR* 127S. Ct. at 1742.

It is additionally noted that the phrases 'quasi-drug' and 'cosmetic' do not impart any structural limitations to the composition save for the fact that the prior art used to reject the claims must not be precluded from use as a 'quasi-drug' or 'cosmetic.' It is clear from the prior art references that the combination does not preclude the composition for use either as a cosmetic or 'quasi-drug.'

Claim 7 which states 'wherein the koji mold is a mold belonging to *Aspergillus oryzae*...' is broad enough to read on wherein the koji mold of the 'processed koji' is prepared by *Aspergillus oryzae*. The product of Ito et al.; kojic acid, is derived from koji. Thus, the 'processed koji' in the instant case, kojic acid, is a processed koji and kojic acid is the same compound independent upon its source or its method of manufacture. It is deemed that kojic acid may be prepared from any koji using any species of *Aspergillus* absent evidence to the contrary.

The Supreme court has acknowledged that:

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. **If a person**

of ordinary skill can implement a predictable variation..103 likely bars its patentability...if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions...

...the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007) emphasis added.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

/Patricia Leith/
Primary Examiner, Art Unit 1655
November 2, 2009